

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Application of: William J. Rea, et al

Attorney Docket: 16715CIP

Serial No.: 08/902,692

Art Group Unit: 1644

Filed: July 30, 1997

Examiner: Schwadron, R., Ph.D.

For: **AUTOGENOUS LYMPHATIC FACTOR FOR MODIFICATION OF
T AND B LYMPHOCYTE PARAMETERS**

DECLARATION OF BERTIE B. GRIFFITHS, PH.D.

1. My name is Bertie B. Griffiths. My residence address is 5602 Willowbrook Dr., Rowlett, Texas 75088. I am over 21 years of age, of sound mind, and competent to make this Declaration.

2. All the statements made in this Declaration made on personal knowledge are true, or, if made on information and belief, are believed to be true.

3. I have a B.S. and M.S. in bacteriology and a Ph.D. in virology. A copy of my curriculum vitae and list of publications is attached.

4. I personally gave a presentation entitled "Laboratory Evaluation of the Phagocytic Function of Environmentally Sensitive Individuals" at The Tenth Annual International Symposium on Man and His Environment in Health and Disease, February 27-March 1, 1992. The published abstract of this presentation was:

The phagocytic killing cascades of 70 environmentally sensitive patients with recurrent infections were investigated. These patients presented multiple manifestations to chemicals, food, inhalants, and recurrent infections. Of these, 88% were found with dysfunctions. Treatment, especially with transfer factor and autogenous vaccines, showed significant improvement in total T cells and phagocytic killing.

I have not been able to locate any copy or notes regarding this presentation, however, based on personal knowledge, the reference to "transfer factor" in this presentation related to a

procedure employing blood obtained from a group of blood donors. "Transfer factor" or the use of blood from a group of donors would not be considered autogenous to a person of skill in the art. The reference to "autogenous vaccines" related to a procedure employing samples of bodily fluids, such as stool or nasal flushing, to obtain micro-organisms afflicting the individual and prepare as vaccines for use in the same individual. No propagation (culturing) of any human cells was encompassed or discussed in making this presentation. The term "autogenous vaccines" as used in this presentation did not refer to the later-invented method regarding "autogenous lymphocytic factor" (aka "ALF").

5. The idea of making an autogenous lymphocytic factor ("ALF") for treating a chemically sensitive or otherwise immunologically compromised individual, including the step of propagating (culturing) of an individual's cells, is described in U.S. patent application Serial No. 08/380,063 filed on January 30, 1995, on which I am a named co-inventor with Dr. William J. Rea. On information and belief, this prior application is referred to as the "parent" of the above-referenced pending application for patent, Serial No. 08/902,692 filed on July 30, 1997, on which I am a named co-inventor with Dr. Rea. The later-filed application adds detail, but, in my opinion, each of the "parent" and the later-filed applications is more than sufficient to disclose to a person of ordinary skill in the art the scope of the invention and how to make and use the invention (without undue experimentation) as defined in the pending claims of this later application, for example the method as set forth in Claim 1:

A method for treating a chemically sensitive individual having an irregular cell cycle for T lymphocytes, the method comprising the steps of:

- (a) collecting a blood sample from the individual;
- (b) determining an initial status of the cell cycle for T lymphocytes;
- (c) isolating mixed T and B lymphocytes from the blood sample;
- (d) propagating the isolated mixed T and B lymphocytes to obtain propagated lymphocytes;
- (e) lysing the propagated lymphocytes to obtain a lysate; and
- (f) administering the lysate to the individual.

6. Neither myself nor Dr. Rea made any publication or commercial use of the invention regarding "ALF" more than one year before the filing date of the "parent" application (i.e., not before January 30, 1994), as supported by the following additional facts.

7. Dr. Rea used himself was the first test subject for ALF, and he was first injected with ALF made from his own blood in early February, 1994. I personally made this very first ALF from a sample of Dr. Rea's blood.

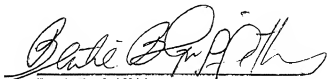
8. In January or February of 1994, a patient of Dr. Rea's was tested and exhibited severe immunological deficiency. I made and supervised the making of ALF from a blood sample taken from this patient, which involved several weeks of propagating (culturing) the patient's lymphocytes in vitro. After preparing the ALF from a sample of the patient's own blood, an injection with this "ALF" was first given to the patient on February 23, 1994. Upon information and belief, Dr. Rea informed the patient that the treatment was experimental.

9. The experiments on Dr. Rea and this patient were the beginning of the first experimental work on patients.

10. The first experimental work regarding "ALF" was not in public use or on sale in any way more than one year before the filing date of the "parent" application for patent (i.e., not prior to January 30, 1994). Upon information and belief, no patient was charged for the first experimental work at any time prior to January 30, 1994 nor was it commercially offered for sale or use.

11. The first publication of any kind regarding "ALF" was my presentation entitled "Prospective Substitution of Transfer Factor with In Vitro Stimulated T Lymphocytes" at The Twelfth Annual International Symposium on Man and His Environment in Health and Disease, February 24-27, 1994. I have been able to locate an audio tape recording of this presentation. This presentation used the word "prospective" in the title and gave only highly preliminary laboratory data on regarding cell cycles. The experimental results regarding the testing on Dr. Rea was the basis for the reported positive results with ALF. This was the first publication of any kind regarding "ALF," which was made less than one year before the filing date of the "parent" application, U.S. patent application Serial No. 08/380,063 filed on January 30, 1995.

12. I hereby declare that all statements made herein of my own knowledge are true, that all statements made on information and belief are believed to be true, and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, and patent issuing thereon, or any patent to which this verified statement is directed.

A handwritten signature in black ink, appearing to read "Bertie B. Griffiths", written over a horizontal line.

Bertie B. Griffiths

04-23-08

Date

BERTIE B. GRIFFITHS, Ph.D.

Education

University of Wisconsin	BS, 1958, Bacteriology
University of Wisconsin	MS, 1960, Bacteriology
University of West Indies	Ph.D., 1972, Virology

Personal

Date of Birth: July 14, 1930
Married to Barbara
Two children

Professional Experience

June 1990 – Present:	Director, North Texas Immunology Laboratory, Environmental Health Center-Dallas, Texas
1978 – 1990:	Associate Professor, Microbiology/Immunology, Oral Roberts University School of Medicine, Tulsa, Oklahoma
1963 – 1978:	Lecturer, Consultant and Clinical Microbiologist, University of West Indies
6/74 – 12/75:	Associate Professor and Consultant Microbiologist, Microbiology/Immunology, Secondment to University of South Alabama, College of Medicine, Mobile, Alabama
1961 – 1974:	Lecturer, Clinical Microbiologist and Director of Arbovirus studies, University of West Indies, Jamaica, W.I.
1958 – 1961:	Research Assistant: Isolation and purification of enzymes from various biological materials at (1) Institute of Enzyme Research, Director, Dr. David Green, University of Wisconsin, (2) Veterans Administration Hospital, Director, Dr. John Porter, Madison, Wisconsin, and (3) Teaching Assistant, University of Wisconsin.

Professional Awards

- June 1990 – Present: National Institute of Health per School of Home Economics, University of Wisconsin (at Robert Taft Engineering Institute, Cincinnati, Ohio and University of Wisconsin, studied clostridial food poisoning)
- 1963: Rockefeller Scholarship to Belem, Brazil and Trinidad, West Indies (training in Arbovirology, Entomology and Tissue Culture).
- 1963: Italian Government to Rome – Istituto de Sanitaria: Dr. Balducci to study virus inhibitors (postponed to take up Rockefeller's).
- 1977: Pan American Health Organizations – offered in 1977 to Germany to study food virology, was unable to pursue it due to domestic obligation.
- 1977: Indefinite Tenure, University of West Indies

Grants

- 1966 – 1968: House of Seagram: *Industrial Microbiology*
- 1974 – 1975: University of South Alabama: *Differences between Herpes Simplex Viruses*
- 1972 – 1976: Jamaica Government: *Arbovirus Surveillance*
- 7/31/85: Intramural Grant Funded: *HSV Relationship to Brain Tumors*
- 4/87: Intramural Grant Funded: *The Role of Iron on Hemolysin Production in Streptococcus pyogenes*
- 6/88: National Institute of Health approved (funding pending availability of funds): *IMMUNOLOGICAL Response of Avians to the EEE Virus*

United States Pending Patent

Cell Cycle Regulation in Clinical Medicine. Submitted January 31, 1995

Representative Publications

- Griffiths, B.B. and McClain, O.: Chromatographic separation of herpes simplex virus, West Ind. Med. Jnl. 33:185-189, 1984
- Griffiths, B.B. and McClain, O.: Immunological response of chickens to eastern equine Encephalomyelitis virus. Research in Vet.Sci.38:65-68, 1988
- Griffiths, B.B. and McClain, O.: The role of iron in the growth and Hemolysin production in *S. pyogenes*. Journal of Basic Microbiology 28:7, 427-436, 1988.
- Griffiths, B.B.: Iron and glucose affecting growth and Hemolysin production in human strains of group β - streptococci. Microbios: 58:135-146, 1989
- Griffiths, B.B.: Chromatographic separation of herpes simplex virus – a novel tool for Differentiation neuropathogenic and non-neuropathogenic strains. Abstr. Ann. Mtg. Am. Soc. For Microbiol., 1988
- Griffiths, B.B. and Rhee: Effects of hemolysins of groups A and B streptococci on cardiovascular system. Microbios: 69:17-27, 1992
- Griffiths, B.B., et al Mitogenic effects of mycotoxins on T_4 lymphocytes. Microbiol: 86:127-134, 1996
- Griffiths, B.B., Rea, William J. The role of T lymphocytes cell cycle and an Autogenous Lymphocytic Factor (ALF) in medicine. Cytobios q3: 49-66, 1998. (patent pending)
- Griffiths, Bradley, and Pan, Y.

Multiple presentations at annual meeting of:

American Society for Microbiology
American Society of Tropical Medicine and Hygiene
American Academy of Environmental Medicine
Various Universities

Multiple presentations at annual meeting given by American Environmental Health Foundation to include:

22nd Annual International Symposium on Man and His Environment, Saturday, June 26, 2004

"Effect of Gamma Globulin in Chronically Sensitized Patients"

21st Annual International Symposium on Man and His Environment, Sunday, June 22, 2003

"Mycotoxins as Vaccine Stimulants"

20th Annual International Symposium on Man and His Environment, Friday, June 7, 2002

"M.I.M. (Mycotic Immune Modulator) it's Role in Clinical Medicine"

19th Annual International Symposium on Man and His Environment, Sunday, June 10, 2001

Title not available at time of printing.

18th Annual International Symposium on Man and His Environment, Sunday, June 11, 2000

"Response of the Cell Cycle to Nutrition"

17th Annual International Symposium on Man and His Environment, Saturday, June 12, 1999

"Cell Cycle & Monocytic Factor-New Concepts on Environmental Medicine"

15th Annual International Symposium on Man and His Environment, Sunday, February 23, 1997

"The Effect of Varied Chemicals and Electro Magnetic Fields on the Cell Cycle"

14th Annual International Symposium on Man and His Environment, February 1996

"Introducing a Functional Cell Cycle"

13th Annual International Symposium on Man and His Environment, February 1995

"Cell Cycles as a Measurement for Cell Function in Chemically Sensitive Patients"

12th Annual International Symposium on Man and His Environment, February 24-27, 1994

"Prospective Substitution of Transfer Factor with *In Vitro* Stimulated T Lymphocytes"

11th Annual International Symposium on Man and His Environment, February 25-28, 1993

"Effects of Mycotoxins on T4 Lymphocytes"

10th Annual International Symposium on Man and His Environment, February 27 – March 1, 1992

"Laboratory Evaluation of the Phagocytic Function of Environmentally Sensitive Individuals"

9th Annual International Symposium on Man and His Environment, February 28 – March 3, 1991

"The Response of Avians to the EEE Virus"